

General Assembly

Substitute Bill No. 505

February Session, 2006

\*\_\_\_\_\_SB00505PS\_\_\_\_041806\_\_\_\_\_\*

## AN ACT CONCERNING THE ESTABLISHMENT OF AN ELECTRONIC PRESCRIPTION DRUG MONITORING PROGRAM AND WORK GROUP.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

- Section 1. Section 21a-254 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2006*):
- (a) The Commissioner of Consumer Protection, after investigation and hearing, may by regulation designate certain substances as restricted drugs or substances by reason of their exceptional danger to health or exceptional potential for abuse so as to require written records of receipt, use and dispensation, and may, after investigation and hearing, remove the designation as restricted drugs or substances from any substance so previously designated.
  - (b) Each physician, dentist, veterinarian or other person who is authorized to administer or professionally use schedule I substances shall keep a record of such schedule I substances received by him and a record of all such schedule I substances administered, dispensed or professionally used by him. The record of schedule I substances received shall in each case show the date of receipt, the name and address of the person from whom received and the kind and quantity of schedule I substances received. The record of all schedule I substances administered, dispensed or otherwise disposed of shall

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- show the date of administering or dispensing, the name and address of the person to whom, or for whose use, or the owner and species of animal for which, the substances were administered or dispensed and the kind and quantity of substances.
  - (c) Practitioners obtaining and dispensing controlled substances shall keep a record of all such controlled substances, received and dispensed by them in accordance with the provisions of subsections (f) and (h) of this section.
  - (d) Manufacturers and wholesalers shall keep records of all controlled substances, compounded, mixed, cultivated or grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them in accordance with the provisions of subsections (f) and (h) of this section.
  - (e) Pharmacies, hospitals, chronic and convalescent nursing homes, rest homes with nursing supervision, clinics, infirmaries, free-standing ambulatory surgical centers and laboratories shall keep records of all controlled substances, received and disposed of by them in accordance with the provisions of subsections (f) and (h) of this section, except that hospitals and chronic and convalescent nursing homes using a unit dose drug distribution system may instead keep such records in accordance with the provisions of subsections (g) and (h) of this section, and except that hospitals and free-standing ambulatory surgical centers shall not be required to maintain separate disposition records for schedule V controlled substances or records of administering of individual doses for ultra-short-acting depressants, including but not limited to, Methohexital, Thiamylal and Thiopental.
  - (f) The form of record to be kept under subsection (c), (d) or (e) of this section shall in each case show the date of receipt, the name and address of the person from whom received, and the kind and quantity of controlled substances received, or, when applicable, the kind and quantity of controlled substances produced or removed from process of manufacture and the date of such production or removal from

process of manufacture; and the record shall in each case show the proportion of controlled substances. The record of all controlled substances sold, administered, dispensed or otherwise disposed of shall show the date of selling, administering or dispensing, the name of the person to whom or for whose use, or the owner and species of animal for which, the substances were sold, administered or dispensed, the address of such person or owner in the instance of records of other than hospitals, chronic and convalescent nursing homes, rest homes with nursing supervision and infirmaries, and the kind and quantity of substances. In addition, hospital and infirmary records shall show the time of administering or dispensing, the prescribing physician and the nurse administering or dispensing the substance. Each such record of controlled substances shall be separately maintained apart from other drug records and kept for a period of three years from the date of the transaction recorded.

- (g) Hospitals using a unit dose drug distribution system shall maintain a record noting all dispositions of controlled substances from any area of the hospital to other hospital locations. Such record shall include, but need not be limited to, the name, form, strength and quantity of the drug dispensed, the date dispensed and the location within the hospital to which the drug was dispensed. Such dispensing record shall be separately maintained, apart from other drug or business records, for a period of three years. Such hospital shall, in addition, maintain for each patient a record which includes, but need not be limited to, the full name of the patient and a complete description of each dose of medication administered, including the name, form, strength and quantity of the drug administered, the date and time administered and identification of the nurse or practitioner administering each drug dose. Entries for controlled substances shall be specially marked in a manner which allows for ready identification. Such records shall be filed in chronological order and kept for a period of three years.
- (h) A complete and accurate record of all stocks of controlled substances on hand shall, on and after July 1, 1981, be prepared

biennially within four days of the first day of May of the calendar year, except that a registrant may change this date provided the general physical inventory date of such registrant is not more than six months from the biennial inventory date, and kept on file for three years; and shall be made available to the commissioner or his authorized agents. The keeping of a record required by or under the federal Controlled Substances Act, or federal food and drug laws, containing substantially the same information as is specified above, shall constitute compliance with this section, provided each record shall in addition contain a detailed list of any controlled substances lost, destroyed or stolen, the kind and quantity of such substances and the date of the discovery of such loss, destruction or theft and provided such record shall be made available to the commissioner or his authorized agents. All records required by this chapter shall be kept on the premises of the registrant and maintained current and separate from other business records in such form as to be readily available for inspection by the authorized agent at reasonable times. The use of a foreign language, codes or symbols to designate controlled substances or persons in the keeping of any required record is not deemed to be a compliance with this chapter.

- (i) Whenever any record is removed by a person authorized to enforce the provisions of this chapter or the provisions of the state food, drug and cosmetic laws for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of three years.
- (j) (1) The commissioner shall, within available appropriations, establish an electronic prescription drug monitoring program to collect, by electronic means, prescription information for schedules II, III, IV and V controlled substances, as defined in subdivision (9) of section 21a-240, that are dispensed by pharmacies and outpatient pharmacies in hospitals or institutions. The program shall be designed to provide information regarding the prescription of controlled substances in order to prevent the improper or illegal use of the controlled substances and shall not infringe on the legitimate

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- prescribing of a controlled substance by a prescribing practitioner acting in good faith and in the course of professional practice.
- 121 (2) Each pharmacy and each outpatient pharmacy in a hospital or 122 institution shall report to the commissioner, at least twice monthly, by 123 electronic means or, if a pharmacy or outpatient pharmacy does not 124 maintain records electronically, in a format approved by the 125 commissioner, the following information for all controlled substance 126 prescriptions dispensed by such pharmacy or outpatient pharmacy: 127 (A) Dispenser identification number; (B) the date the prescription for the controlled substance was filled; (C) the prescription number; (D) 128 whether the prescription for the controlled substance is new or a refill; 129 130 (E) the national drug code number for the drug dispensed; (F) the 131 amount of the controlled substance dispensed and the number of days' 132 supply of the controlled substance; (G) a patient identification number; (H) the patient's first name, last name and street address, including 133 134 postal code; (I) the date of birth of the patient; (I) the date the prescription for the controlled substance was issued by the prescribing 135 practitioner and the prescribing practitioner's Drug Enforcement 136 137 Agency's identification number; (K) the name of the person receiving 138 the controlled substance from the dispenser, if other than the patient; (L) the type of payment for the controlled substance and the name of 139 140 the governmental program or health insurer paying for the controlled 141 substance, if applicable; and (M) the state issued serial number, if 142 applicable.
- (3) The commissioner may contract with a vendor for purposes of
  electronically collecting such controlled substance prescription
  information. The commissioner and any such vendor shall maintain
  the information in accordance with the provisions of chapter 400j.
  - (4) The commissioner and any such vendor shall not disclose controlled substance prescription information reported pursuant to subdivision (2) of this subsection, except as authorized pursuant to the provisions of sections 21a-240 to 21a-283, inclusive. Any person who knowingly violates any provision of this subdivision or subdivision (3)

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of this subsection shall be guilty of a class D felony.

- 153 (5) The commissioner shall provide, upon request, controlled 154 substance prescription information obtained in accordance with subdivision (2) of this subsection to the following: (A) The prescribing 155 156 practitioner who is treating or has treated a specific patient, provided 157 the information is obtained for purposes related to the treatment of the 158 patient, including the monitoring of controlled substances obtained by 159 the patient; (B) the prescribing practitioner with whom a patient has made contact for the purpose of seeking medical treatment, provided 160 the request is accompanied by a written consent, signed by the 161 162 prospective patient, for the release of controlled substance prescription 163 information; or (C) the pharmacist who is dispensing controlled 164 substances for a patient, provided the information is obtained for purposes related to the scope of the pharmacist's practice and 165 management of the patient's drug therapy, including the monitoring of 166 167 controlled substances obtained by the patient. The prescribing practitioner or pharmacist shall submit a written and signed request to 168 the commissioner for controlled substance prescription information. 169 170 Such prescribing practitioner or pharmacist shall not disclose any such 171 request except as authorized pursuant to sections 20-570 to 20-630, 172 inclusive, or sections 21a-240 to 21a-283, inclusive.
- 173 (6) The commissioner shall adopt regulations, in accordance with 174 chapter 54, concerning the reporting, evaluation, management and 175 storage of electronic controlled substance prescription information.
  - Sec. 2. (NEW) (Effective October 1, 2006) The Commissioner of Consumer Protection shall appoint a prescription drug monitoring working group for the purpose of advising the commissioner on the implementation of the electronic prescription drug monitoring program established pursuant to section 21a-254 of the general statutes, as amended by this act, including the adoption of regulations by the commissioner. Such advice shall include, but not be limited to, recommendations on how to effectively use the data collected pursuant to such program to detect fraud while protecting the

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185 legitimate use of controlled substances. The working group shall 186 include, but not be limited to: (1) A physician, licensed pursuant to 187 chapter 370 of the general statutes, specializing in internal medicine; (2) a board certified oncologist; (3) a person licensed to perform 188 advanced level nursing practice activities pursuant to subsection (b) of 189 190 section 20-87a of the general statutes; (4) a representative from an acute 191 care hospital licensed pursuant to chapter 368v of the general statutes; 192 (5) a state police officer appointed in accordance with section 29-4 of 193 the general statutes; (6) a municipal police chief; (7) a representative 194 from the Division of Criminal Justice; (8) a representative from a 195 hospice licensed by the Department of Public Health or certified 196 pursuant to 42 USC 1395x; (9) a pain management specialist, as defined in section 38a-492i of the general statutes; (10) a pharmacist licensed 197 198 pursuant to section 20-590, 20-591 or 20-592 of the general statutes; and 199 (11) a representative from the Department of Mental Health and 200 Addiction Services.

This act shall take effect as follows and shall amend the following sections:		
Section 1	October 1, 2006	21a-254
Sec. 2	October 1, 2006	New section

GL Joint Favorable Subst.

JUD Joint Favorable

PS Joint Favorable